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Guidance for the Reregistration of Pesticide Products Containing Asulam as the Active Ingredient

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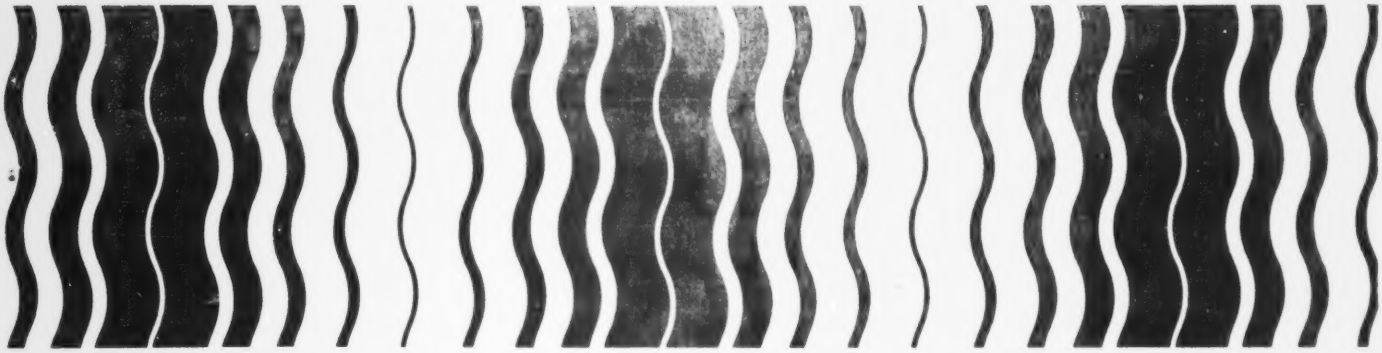
Guidance for the Reregistration of Pesticide Products Containing Asulam as the Active Ingredient



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GUIDANCE FOR THE REGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

ASULAM

OR

SODIUM SALT OF ASULAM

AS THE ACTIVE INGREDIENT

OPP NO. 106901, 106902
CAS NO. 3337-71-1, 2302-17-2
CASE NO. 0265

DECEMBER, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment such as a terrestrial or aquatic ecosystem.
EP	End-use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon-request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of the Chemicals

The following chemicals are covered by this Registration Standard:

Common Names: asulam and sodium salt of asulam
Chemical Name: methyl sulfanilylcarbamate and sodium salt of methyl sulfanilylcarbamate
Empirical Formula: $C_8H_{10}N_2O_4S$ (asulam)
Molecular Weight: 230.2 (asulam)
Chemical Class: Carbamate
Chemical Abstracts Service (CAS) Number: 3337-71-1 (asulam)
2302-17-2 (sodium salt of asulam)
OPP (Shaughnessy) Number: 106901 (asulam)
106902 (sodium salt of asulam)
Trade Name: Asulox

B. Use Profile

Asulam is a selective postemergent herbicide registered for the control of certain broadleaf weeds, perennial grasses and non-flowering plants. The herbicide may be used on sugarcane, noncrop areas such as rights-of-way, forestry sites (Christmas tree plantations, site preparation, and conifer release), ornamentals, established turf, and ditchbanks. Asulam's mode of activity involves interference with the process of plant cell division and expansion in the meristematic regions of plants -- the growing points or areas of rapidly dividing cells at the tip of a stem, root or branch. It appears to exhibit maximum herbicidal activity when applied to actively growing immature weeds. Asulam was initially registered in 1975 and is available as a 86.4% active ingredient (a.i.) technical/manufacturing-use product and an end-use product containing 36.2% (a.i.) soluble concentrate/liquid of the sodium salt of asulam (equivalent to 3.34 pounds of active ingredient per gallon).

Asulam is used principally on sugarcane, with this use representing roughly 90% of total usage. The majority of asulam applied to sugarcane is in Florida where sugarcane acreage accounts for 50% of total U. S. acreage. It is also used in the production of sugarcane in Louisiana and Texas; relatively little asulam is used on sugarcane grown in Hawaii. The remaining 8 to 9% of total asulam used is applied to noncrop sites, particularly commercially produced turf.

Asulam can be applied by surface spray or aerial equipment. It may also be applied as a spot treatment. Application rates vary from 1.67 to 6.68 pounds active ingredient/acre depending upon the use pattern and target weed species.

III. AGENCY ASSESSMENT

A. Summary

Based on a review of existing data submitted to support registration of asulam, the Agency has reached the following conclusions. The following is only a summary. A more detailed discussion is contained in sections B and C of this chapter.

1. Asulam produced oncogenic effects in a rat long-term feeding study. In the rat, there was a statistically significant increase in thyroid C-cell carcinomas and combined C-cell adenomas/carcinomas in males at the low and mid doses and a statistically significant increase of benign pheochromocytomas of the adrenal medulla and combined benign/malignant pheochromocytomas in males at the highest dose tested. In a mouse oncogenicity study, compound-related statistically significant increase in tumors was not produced; however, due to deficiencies a repeat study is required. Asulam was tentatively classified as a Category C oncogen (limited evidence of carcinogenicity in animals).

2. Available data are insufficient to fully assess the environmental fate of asulam. However, preliminary data indicate that asulam may have the potential to contaminate ground water. Additional data are required before the Agency can fully evaluate this environmental fate characteristic. In addition, there is preliminary evidence from rotational crop data that asulam residues may occur in crops rotated on asulam-treated fields.

3. Avaiable ecological effects data show that asulam is practically non-toxic to avian species, warmwater fish and honey bees. There is no evidence that asulam poses a threat to endangered or threatened plant or animal species.

As a result of this review the Agency has identified missing data necessary to evaluate the environmental and human health risks associated with the use of asulam. These data must be developed in order to maintain registrations of products or register new products containing asulam. A summary of these data gaps appears in Table 1. Please note that this is only a summary; complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that, based on existing data, no unique label statements, other than rotational crop restrictions, are necessary.

The Regulatory Position and Rationale section discusses the Agency's position regarding the regulation of asulam.

TABLE 1
SUMMARY OF DATA GAPS FOR ASULAM

(Refer to Appendix I, Data Tables, for
detailed information and due dates)

Product Chemistry -- All

Residue Chemistry -- Animal Metabolism
Residue Analytical Methods
Magnitude of Residues

Environmental Fate -- Hydrolysis
Photodegradation (water, soil)
Aerobic and Anaerobic Soil Metabolism
Aerobic and Anaerobic Aquatic Metabolism
Leaching and Adsorption/Desorption
Small-scale Prospective Field Leaching Study
Field Dissipation (aquatic sediment and forestry)
Rotational Crops (confined and field)
Irrigated Crops

Toxicology -- Acute Toxicity
Subchronic Toxicity (21-day dermal)
Chronic Toxicity (non-rodent)
Oncogenicity (mouse)
Mutagenicity (Ames test and chromosomal aberration)
General Metabolism

Ecological Effects -- Freshwater Fish LC_{50} (coldwater fish)
Acute LC_{50} Estuarine and Marine Organisms (oyster study)
Acute LC_{50} Freshwater Invertebrates

B. Toxicological Assessment

In its toxicological evaluation of asulam, the Agency considered the following data.

Rat Chronic Feeding/Oncogenicity

In this study, Sprague Dawley CR-CD rats (50 per dosage group) were fed doses of 0, 1000, 5000, or 25000 ppm asulam in the diet for two years. Results show that asulam caused a carcinogenic effect in the endocrine system of male rats. There was an increased incidence of thyroid C-cell carcinomas and combined C-cell adenomas/carcinomas in low- and mid-dose males which was statistically significant, even though no dose response for this effect was noted and the incidence decreased at the high dose. The data also show that asulam caused an increased incidence of benign adrenal medullary pheochromocytomas and combined benign/malignant pheochromocytomas in male rats at the high dose. Supporting evidence includes increased adrenal medullary hyperplasia in the mid- and high-dose groups. Non-neoplastic histopathology also included increased thyroid follicular hyperplasia in the high dose males. These data are summarized in Table 2.

The elevated incidences of thyroid C-cell carcinomas at low and mid doses and benign adrenal pheochromocytomas at high dose exceeded historical control range values for the tumor types in male Sprague Dawley CR-CD rats.

Systemic effects observed in this study include decreased body weight gain with a no-observed-effect-level (NOEL) of 1000 ppm from weeks 0 to 52.

Mouse Oncogenicity

In this study, 60 per dose/sex Carworth CF-1 albino mice were fed 0, 1500, or 5000 ppm asulam in the diet for 78 weeks. Results showed a statistically significant positive dose-related trend for undifferentiated sarcoma of the skin and subcutis in male mice by analysis with Cochran-Armitage Trend Test. However, the increased incidence of these tumors at 5000 ppm was not statistically significantly different from concurrent control level by the Fisher-Exact Test. These data are summarized in Table 3.

These tumors were not considered compound-related because 1) they occurred only at the high dose in a low incidence, 2) the incidence was not statistically significant and 3) a parasitic skin infection was present which could have been related to the occurrence of skin tumors.

A repeat mouse oncogenicity study is required due to the following deficiencies. (1) the use of only two dose levels rather than the three required by EPA; (2) evidence that the test animals were in poor health as demonstrated by chronic kidney inflammation in males and females and parasitic infection of the skin, colon, and small intestines of males; (3) the maximum tolerated dose (MTD) was not achieved.

Several chemicals that are structurally related to asulam produce thyroid tumors in rodents. These include the herbicide oryzalin (a Category C oncogen) and the sulfonamide drug Sulfamethoxazole. Sulphisoxazole, another sulfonamide was negative for oncogenicity in rats and mice. The induction of thyroid tumors by oryzalin and sulfamethoxazole was considered to be due to indirect anti-thyroid effects.

The Agency has conducted a weight-of-the evidence evaluation of the oncogenic potential of asulam. According to EPA Guidelines for Carcinogenic Risk Assessment (September 24, 1986, 51 FR 33992), asulam was tentatively classified as a Category C oncogen (limited evidence of carcinogenicity in animals). Tumors were produced in only one strain and sex of rodent, and in only a single experiment. Neither of the tumor responses occurred in a strictly dose-related fashion. Both of the tumors were of a relatively common type and there was no apparent decrease in latency. In addition short term tests for mutagenicity were negative. This categoriaztion will be reevaluated upon receipt of the repeat mouse study. Because of this rather limited evidence, quantification of human risk was considered inappropriate.

TABLE 2

(Summary of Tumor Incidence in the Rat
Chronic Feeding/Oncogenicity Study)

	Dose (ppm) Males			
Tumor Type	0	1000	5000	25000
Thyroid				
C-Cell Adenoma	0/43(0%)	4/43(9%)	2/43(5%)	0/40(0%)
C-Cell Carcinoma	0/34(0%)	5/38(13%)[a]	5/31(16%)[a]	2/33(6%)
Combined	0/43(0%)	9/43(21%)[b]	7/43(16%)[b]	2/40(5%)
Adrenal Pheochromocytoma				
Benign[c]	3/44(7%)	4/44(9%)	4/45(9%)	10/43(23%)[a]
Malignant	0/30(0%)	1/36(3%)	0/26(0%)	0/32(0%)
Combined[c]	3/44(7%)	5/44(11%)	4/45(9%)	10/43(23%)[a]

a= $p < 0.05$, b= $p < 0.01$, Fisher's Exact Test; c= Statistically significant positive dose-related trend ($p<0.05$); Cochran - Armitage Trend Test

TABLE 3

(Skin Tumors in Mouse Oncogenicity Study)

Tumor Type	Dose Level (ppm) 0	1500	5000
Undifferentiated Sarcoma of Skin and Subcutis[c]	0/41(0%)	0/49(0%)	4/46(8.7%)

c= Statistically significant positive dose-related trend ($p<0.05$); Cochran - Armitage Trend Test

Note: The incidences depicted in the tables above refer to the number of tumor bearing animals (numerator)/number examined (denominator).

Subchronic Toxicity

Only supplementary information is available to assess the subchronic effects of exposure to asulam. However, a six-month dog study may be upgraded to fulfill both nonrodent subchronic and chronic testing. In this study, six beagle dogs/sex/dose level were fed 0, 60, 300, and 1500 mg/kg/day asulam in the diet. Low-dose females were found to have increased thyroid weights, which were also found in both males and females at the high dose. Relative thyroid/body weight ratio was increased at 1500 mg/kg/day in males and females, and mean bodyweight gain at 1500 mg/kg/day was lower in males and females when compared to controls. The tentative NOEL is therefore 60 mg/kg/day. As indicated above, this study may be upgraded upon receipt of appropriate clinical measurement summary tables and other data described in the Data Tables.

Teratogenic and Reproductive Effects

Teratology studies conducted in the rat and the rabbit show no evidence that asulam causes developmental effects. In a study with rabbits, the animals were administered asulam at levels of 0, 150, 300, and 750 mg/kg/day. The NOEL's for maternal toxicity and developmental toxicity (fetotoxicity) were 750 mg/kg/day, the highest dose tested. In a rat teratology study, the animals were administered 0, 50, 1000, and 1500 mg/kg/day. The NOEL's for both maternal toxicity and developmental toxicity were 1500 mg/kg/day, the highest dose tested.

In a 2-generation reproductive effects study, asulam was administered to rats at doses of 0, 1000, 5000, and 25000 ppm. The NOEL for reproductive effects was 1000 ppm based on the incidence of fewer live births per litter at the 5000 and 25000 ppm dose levels. There was also a slightly lower fertility index in F_1 parents (second generation) at 5000 and 25000 ppm. After statistical analysis of the lower fertility index, the Agency determined that there was no significant difference in the average litter size between the controls and the low dose group (1000 ppm) for the F_1 females when tested by the one sided t-test. The mean litter size of the control group, 11.33, was not significantly different from the 1000 ppm mean, 10.32 (p=.218 [one sided t value]). There were 18 litters in the control group and 19 litters in the dose group. The test for equality of variances was not significant (p=.12). Asulam therefore has not been shown to impair reproductive ability. A systemic NOEL was not observed due to relative female liver weight which was significantly lower than controls in low, mid and high doses.

Mutagenic Studies

Three mutagenicity studies were reviewed for asulam -- an Ames test, a cell transformation assay to assess primary DNA damage, and a chromosomal aberration assay. Only the cell transformation assay was acceptable and was negative for mutagenic effects. Additional data are required to fully assess the mutagenic potential of asulam. If individual animal data can be provided, a dominant lethal study may be upgraded to satisfy the chromosome aberration requirement.

Metabolism

No acceptable data are available to evaluate the metabolism of asulam. The only data available were an elimination study (invalid) and an absorption, excretion, and metabolism study (supplementary). The latter showed that asulam is not completely eliminated in a repeated dose regimen after more than 3 days of administration to rats. There was some evidence of accumulation in blood and fat. However, since only 3 rats were used in this study, the data provided are only of limited value. A metabolism study is therefore required.

Acute Toxicity

The acute toxicity properties of asulam are not completely known. There are no data available to assess the acute oral, dermal and inhalation toxicity of asulam. Primary eye and dermal irritation studies show that asulam is of low toxicity (Toxicity Categories III and IV, respectively). A dermal sensitization study showed that asulam is not a sensitizing agent. Additional data are required.

C. OTHER SCIENCE FINDINGS

Environmental Fate

Data to assess adequately the environmental fate of asulam are unavailable. Data are required as specified in Table A.

Several environmental fate studies were reviewed. Except for a leaching and adsorption/desorption study which was partially acceptable, studies were not adequate when measured against current testing guidelines. Though asulam has not been found in ground water, partially acceptable data show that the chemical is mobile to very mobile in sand, loamy soil, loam and clay loam soil. In soil columns both the parent compound and degradates leached and were found as 19-88% of the applied material in the column leachates. Asulam appears to be resistant to natural sunlight photolysis, and may be resistant to hydrolysis. Asulam is rapidly degraded in soil under aerobic conditions. The half-life appears to range from one to several days; most of the degraded material becomes tightly bound to the soil. Under anaerobic (flooded) conditions, the amount of bound residues appears to decrease and the degradation rate decreases. Results of a field dissipation study appear to indicate that asulam residues may move past the 0-6 inch sampling depth to the 12-24 inch sampling depth. Because these data are largely inconclusive, however, a ground water monitoring study is being required to track the movement of residues of asulam and its degradates in soil, soil-pore water, and shallow ground water.

In addition, although crop rotational data do not meet EPA's current testing standards, available data indicate that residues may occur in crops grown in areas treated in prior years with asulam. The potential for asulam residues to carry over to subsequent crops will be more fully evaluated when the required rotational crop data are submitted to the Agency.

Ecological Effects

While the ecological effects data on asulam technical are limited, data exist on formulated products containing 40% or 60% asulam which can be utilized to satisfy several ecological effects data requirements. The Agency has reached the following conclusions based on available data.

1. Toxicity to Birds. Data on asulam technical are insufficient. However, several studies conducted with formulated products containing 40% or 60% asulam are adequate to use for a hazard assessment. These data show that asulam is practically non-toxic to upland game birds and water fowl on an acute and dietary basis. LD_{50} values were greater than 4000 mg/kg for mallard

duck, partridge, pheasant and pigeon. LC_{50} values were greater than 75,000 ppm for pheasant and mallard duck. When these figures are adjusted to account for exposure to 100% asulam the values were estimated to be 1600 mg/kg and 45,000 ppm, respectively. These values are still within the low toxicity range and demonstrate that asulam is not expected to adversely affect avian wildlife.

2. Toxicity to Aquatic Organisms

Asulam technical is practically non-toxic to warmwater fish with an LC_{50} value of >180 ppm for bluegills. There is a data gap for toxicity to coldwater fish and such data are being required.

A study on the acute toxicity of technical asulam to aquatic invertebrates demonstrated that the chemical is slightly toxic to *Daphnia magna* with an acute LC_{50} of 27 ppm. However, this study was invalidated by a laboratory audit and thus must be replaced.

Acute LC_{50} studies with estuarine/marine species show that technical asulam is practically nontoxic to fiddler crabs (>100 ppm) and grass shrimp (>100 ppm). However, data are also required to assess toxicity to oysters.

3. Toxicity to Bees

An acceptable acute contact study demonstrated that asulam is relatively nontoxic to honey bees (1.28% mortality at 36.26 micrograms per bee). No additional data are required.

In summary, based on information about the use patterns of asulam, the estimated environmental concentrations of its residues, and available toxicity data, the Agency does not expect that the use of asulam will pose a hazard to endangered terrestrial wildlife species or aquatic organisms, but requires additional data to be certain.

D. TOLERANCE REASSESSMENT

A tolerance of 0.1 ppm has been established for residues of asulam in or on sugarcane (40 CFR Part 180.360). No Mexican tolerance or Codex MRL exists for residued of asulam in or on sugarcane. Therefore, no compatibility questions exist with respect to the Codex MRL. A negligible residue tolerance is in effect in Canada for asulam residues in or on flax. EPA has evaluated the data supporting the tolerances and has reached the following conclusions.

Residue Data. The residue data reviewed in support of this tolerance indicate the following:

1. The metabolism of asulam in sugarcane is adequately understood. Asulam undergoes a complex degradative pathway involving hydrolysis of the carbamate ester, hydroxylation, and subsequent transformation into naturally occurring plant constituents. The major residues are the parent compound and six of its sulphanilamide-containing metabolites. The single tolerance for residues in or on sugarcane is currently expressed in terms of asulam *per se*.*

2. The metabolism of asulam in animals is not completely understood. Available data adequately depict metabolism of asulam only in ruminants (goats). These data show that greater than 91% of administered [^{14}C] asulam was eliminated by two goats in urine and feces within 7 days of dosing at 5 mg/kg, equivalent to roughly 100 ppm in the diet. Residues in tissues were ≤ 8 ppm at 17 hours and <0.45 ppm at 7 days post dosing. Asulam and some of its metabolites were detected in goat liver, and metabolites only in goat kidney and milk. No data have been submitted which depict the nature of asulam residues in poultry meat, fat, meat by-products, or eggs. Additional data are required.

3. Available data are insufficient to assess the adequacy of the established tolerance for residues of asulam in or on sugarcane because the data reflect application rates either lower or higher than the maximum registered rate and collection of samples at post treatment intervals significantly shorter or longer than the established 90-day pre-harvest interval (PHI).

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* It should be noted also that tolerance petitions are currently pending for the combined residues of asulam and its metabolites containing the sulfanilamide moiety as asulam equivalents in and/or on: alfalfa, fresh; alfalfa, hay; clover, fresh; clover, hay, flaxstraw; flaxseed; meat, fat and meat by-products of cattle hogs, horses, sheep and goats; meat, fat and meat by-products of poultry; milk; and eggs. The data submitted to support these proposed tolerances have not been included in the registration standard review.

In addition, available processing studies are inadequate because residues of asulam were not determined in bagasse, molasses, or refined sugar processed from sugarcane bearing measurable residues. Data depicting asulam residues on the raw agricultural commodity sugarcane and processed products are required.

4. Adequate spectrophotometric methods exist for collection of data on asulam residues in or on sugarcane and its processed products and in animal commodities. However, asulam has not been analyzed by multiresidue methods as required by the residue chemistry data requirements (40 CFR 158.125). Residues of asulam in or on sugarcane samples must therefore be subjected to analysis by multiresidue protocols.

5. Available data are sufficient to determine that residues of asulam per se are stable in or on frozen plant commodities for up to 13 months, in milk for 1 week and in animal tissue for up to 1 month. However, all residue data requested in this registration standard must be accompanied by data regarding length and conditions of sample storage.

Acceptable Daily Intake: The toxicological data for asulam are insufficient to determine an Acceptable Daily Intake (ADI). However, a Provisional Acceptable Daily Intake (PADI) has been calculated based on a 2-generation reproductive effects study with a reproductive NOEL of 50 mg/kg/day (1000 ppm) and using an uncertainty factor of 1000. Because this study did not establish a systemic NOEL a 10-fold uncertainty factor was used in addition to the 100-fold factor used to account for gaps in the data base. The PADI with a 1000-fold safety factor is calculated to be 0.05 mg/kg/day. A comparison of the published tolerance to the PADI was conducted using the Tolerance Assessment System Routine Chronic Analysis. Based on the analysis, a Theoretical Maximum Residue Contribution (TMRC) for the U.S. population was calculated to be 0.0001837 mg/kg/day, which utilizes 0.3673 percent of the PADI. Using the TMRC provides a conservative estimate since it does not consider the effect of processing on residue levels in the raw agricultural commodity, that actual residue levels may be lower than the established tolerance, and that less than 100 percent of the crop is treated.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationale

Based on the review and evaluation of all available data on asulam, the Agency has made the following determinations. Where label revisions are imposed, specific language is set forth in Section C of this Chapter.

1. The Agency will not begin a special review of asulam at this time.

Rationale: Although asulam is oncogenic to rats, it does not meet the criterion in 40 CFR 154.7(b)(2) for starting a special review based on this effect. EPA's special review rules provide that the Administrator may conduct a special review if a pesticide use "may pose a risk of inducing in humans an oncogenic...effect, which is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk..." (50 FR 49016, November 27, 1985). EPA concludes at this time that the risk of oncogenic effects from exposure to asulam is not of sufficient concern to warrant a special review. Further, asulam does not meet any other criteria for special review at this time.

2. The Agency is concerned that asulam has the potential to leach to ground water and is requiring small-scale field leaching studies to assess further this environmental fate characteristic.

Rationale: Laboratory column leaching data indicate that asulam is mobile to very mobile in sand, loamy soil, loam and clay loam soil. Field dissipation studies indicate that asulam may move to a 12-24 inch sampling depth. In view of these facts and other known environmental characterisics of asulam, the Agency determined that small-scale leaching studies (in lieu of further soil dissipation studies) must be conducted to track the movement of residues of asulam and its degradates in soil, soil-pore water, and shallow ground water. Since the required data are intended to further clarify the incomplete data on the leaching potential of asulam, the Agency is not requiring interim label advisory statements at this time.

3. The Agency is imposing rotational crop restrictions on asulam.

Rationale: As discussed in Part III,C. of this document, there is evidence from studies which are scientifically sound (although not satisfying EPA's current testing guidelines) that asulam residues accumulated in rotational crops grown in soil with both 124-day and 248-day treatment-to-planting intervals. Therefore, a one year crop rotation restriction must appear on the label. If the results of additional crop rotation data required by this standard indicate that residues will occur in crops planted more than one year after asulam application, a tolerance must be obtained for the rotated crop.

4. The Agency is requiring additional data on the metabolism of asulam in animals and may, upon review of these data, amend the tolerance expression (asulam _per se_) for sugarcane to include metabolites of toxicological significance.

Rationale:

The metabolism of asulam in animals is not completely understood. There are sufficient data to depict the animal metabolism of asulam in ruminants (goats). Data are required to identify and quantify asulam residues in poultry. The metabolism of asulam has been sufficiently delineated in sugarcane, where studies have identified six of asulam's sulphaniliamide-containing metabolites. Depending upon the results of the animal metabolism studies and the toxicological significance of the metabolites, the tolerance expression may require amendment to include both the parent compound and metabolites.

5. The Agency is requiring additional data to support the existing tolerance for residues of asulam on sugarcane.

Rationale: A review of the available data indicates that the Agency does not have sufficient residue data to support the established tolerance for asulam on sugarcane.

6. The Agency is requiring processing studies to determine residues of asulam in bagasse, molasses, and refined sugar processed from sugarcane bearing measurable residues.

Rationale: Existing data are insufficient to determine whether residues of asulam concentrate in these processed products of sugarcane.

7. The Agency is requiring that residues of asulam in or on sugarcane be subjected to analysis by multiresidue protocols.

Rationale: Adequate spectrophotometric methods exist for collection of data on asulam residue in or on sugarcane and its processed products and in animal commodities. However, asulam residues have not been analyzed by multiresidue methods as required by the residue chemistry data requirements set forth in 40 CFR 158.125.

8. The Agency is requiring that all labels of end-use products containing asulam registered for use on sugarcane continue to restrict application to 90 days before harvest and restrict the grazing of sugarcane and feeding of fodder and forage to livestock.

Rationale:

While residue chemistry and toxicological data are generated and evaluated, current label restrictions will limit the possibility of impermissible residues in food or feed.

9. The Agency will not require reentry protection data to be submitted or impose an interim reentry interval for asulam products at this time.

Rationale:

Asulam does not meet the 40 CFR 158.140 criteria for submitting reentry data: Although there are data gaps acute toxicity appears to be low (Toxicity Category III & IV by primary eye and dermal irritation, and not a sensitizing agent). Little reentry exposure would be expected from early postemergent use of asulam on non-crop and sugarcane sites. Current practices in sugarcane include hand-harvesting, but sugarcane is burned standing in fields before harvest. Burning will result in dissipation of the pesticide and removal of pesticide treated foliage.

10. The Agency will not require a restricted use classification for asulam end use products.

Rationale:

Asulam is not acutely toxic in avaiable studies, and, therefore, does not meet the criteria (40 CFR 162.11) for a restricted use classification.

11. The Agency will not establish any new food/feed additive regulations pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Rationale:

The Delaney Clause in section 409 of the FFDCA bars the establishment of food additive regulations for substances which induce cancer in man or test animals, with certain exceptions which may not apply here. The Agency is currently developing a position relative to the Delaney Clause and FIFRA. Once this policy has been established, the Agency will determine what action is required in relation to pesticides which have induced positive oncogenic responses in chronic animal studies.

12. While the data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing asulam as the sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this Registration Standard. Registrants must provide or agree to develop additional data, as specified in Table A of the appendices, in order to maintain existing registrations.

The Agency will issue registrations for substantially similar products. However, new uses will be approved only on a case-by-case basis after considering the effect on the theoretical maximum residue contribution (TMRC), the maximum permissible intake (MPI), and the oncogenic risks.

Rationale:

While the currently available data are not adequate to support the registration of any registered asulam product unconditionally under FIFRA section 3(c)(5), the available data do support the conditional registration of all of the currently registered products. Under the FIFRA, the Agency does not normally cancel or withhold registration merely because data are missing or inadequate [see FIFRA sections 3(c)(2)(B) and 3(c)(7)]. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated. The Agency will then determine whether additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be covered under the Standard, manufacturing-use products must contain asulam as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Appendix III, EPA Index to Pesticide Chemicals.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products must contain asulam as the sole active ingredient. Each manufacturing-use formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing asulam, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed, as required by 40 CFR 162.10.

3. Use Patterns

To be registered under this Standard, technical grade or manufacturing-use products containing asulam may be labeled for formulation into end-use products registered for the uses listed in Appendix III, EPA Index to Pesticide Chemicals -- Asulam. This index lists all registered uses, as well as the approved maximum application rates and frequencies.

General use patterns included in Appendix III include: terrestrial food crop (agricultural crops); terrestrial nonfood crop (ornamental plants and forest trees, noncrop, wide area, and general indoor/outdoor treatments); aquatic nonfood (aquatic sites); and forestry.

D. LABELING

In order to remain in compliance with FIFRA, manufacturing-use products and end-use products as covered by this Standard, must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

Pesticide products containing asulam may not be released for shipment by the registrant after February 1, 1989 unless the product bears an amended label which complies with the requirements of this Standard.

Pesticide products containing asulam may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received (and having been so received) delivered, or offered to be delivered by any person after February 1, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling of manufacturing-use and end-use products as specified below.

1. Ingredient Statement

MPs must list the active ingredient as:

Asulam: methyl sulfanilylcarbamate..................%

EPs must list the active ingredient as:

Sodium salt of asulam (methyl sulfanilylcarbamate)....%

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

The labels of a technical grade or manufacturing use product must bear statements reflecting the compound's acute human toxicity, as specified in 40 CFR 162.10, and statements pertaining to environmental hazard. In addition, the label of each manufacturing-use product must contain the following environmental statement:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing the product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Statements for End Use Products.

The following statements must appear on the label of each product:

"Do not apply directly to water or wetlands (swamps, bogs, lagoons, marshes, or potholes). Do not clean equipment or dispose of equipment washwater in a manner that will contaminate water resources."

"Do not rotate with any crop which is not registered for use with Asulam for one year following the last application of this chemical."

"Do not treat sugarcane within 90 days of harvest. Do not graze or feed sugarcane forage and fodder to livestock."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide

EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other

[redacted]

registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months of receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

Within 9 months from the receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

F. Addresses

The required information must be submitted to the following address:

Richard F. Mountfort (PM-23)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

APPENDIX I

DATA TABLES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data Be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	N/A	N/A	Yes2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes3/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes4/	6 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	N/A	N/A	Yes5/	12 Months
62-2 - Certification of Limits	TGAI	All	N/A	N/A	Yes6/	12 Months
62-3 - Analytical Method	TGAI	All	N/A	N/A	Yes7/	12 Months
Physical and Chemical Characteristics:						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 months
63-5 - Melting Point	TGAI	All	N/A	N/A	Yes8/	6 Months
63-6 - Boiling Point	TGAI	All	N/A	N/A	Yes9/	6 Months
63-7 - Density Bulk Density, or	TGAI	All	N/A	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued):						
Physical and Chemical Characteristics (Continued):						
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	N/A	N/A	Yes[10]	6 Months
63-12 - pH	TGAI	All	N/A	N/A	Yes[11]	6 Months
63-13 - Stability	TGAI	All	N/A	N/A	Yes	6 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No	

---

[1] Not applicable. Although product Chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[2] The nominal concentration for each active ingredient, and the names of each impurity for which a certified limit is required must be submitted.

[3] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier or each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

§158.120 Product Chemistry (Continued):

4/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at $\geq$0.1% (w/w). Complete validiation data (accuracy, precision) must be submitted for each analytical method used.

6/ For each registered technical, upper and lower limits for asulam, and upper limits for each impurity present at $\geq$0.1% (w/w), and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA Form 8570, Rev. 2/85.

7/ For each registered technical, analytical methods to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required must be submitted. Each method must be accompanied by validation studies indicating its accuracy and precision, so as to be suitable for enforcement of certified limits.

8/ Data needed if the technical chemical is a solid at room temperature.

9/ Data needed if the technical chemical is a liquid at room temperature.

10/ Required if the technical chemical is organic and non-polar.

11/ Required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission1/
§158.125 Residue Chemistry					
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Yes	00024737 00044583 00052044 00056424 00056425 00113828	No	
- Livestock	PAIRA	Partially	00044580 00056422 00098551	Yes2/	18 Months
171-4 - Residue Analytical Method - Plant residues - Animal residues	TGAI and Metabolites	Partially	00004821 00004822 00044584 00056432 00056435 00056436 00056438 00056439 00056440 00084804 00084790 00098545 00098547 00098548 00098550 00098552 00098553 00113827 00113831	Yes3/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission1/
§158.125 Residue Chemistry Continued:					
171-4 - Storage Stability Data	PAI or TEP Metabolites	Partially	00052047 00098549 00098551	Yes4/	18 Months
171-4 - Magnitude of the Residue in Plants -- Miscellaneous Commodities					
- Sugarcane	TEP	Partially	00004821 00004823 00004824 00056441 00056442 00113830 00113836 00113837 00136346	Yes5/	18 Months
	EP	Partially	00056441 00113831 00113836	Yes6/	24 Months
171-4 - Magnitude of the Residue in Meat/ Milk/Poultry/Eggs	TGAI or Plant Metabolites	Yes	00052047 00084805 00098553 00113833	Reserved7/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

§158.125 Residue Chemistry (Continued):

1/ For Nature of the Resdiue in Plants and Magnitude of the Residue in Crops, the timeframes for submitting data are 18 or 24 months, as appropriate commencing with the first planting season following issuance of this registration standard.

2/ Data must be submitted depicting the nature of asulam in meat, fat, and meat by-products and eggs of poultry. Animals must be dosed for at least 3 days at a sufficient levels to insure residue quantification and identification. Eggs must be collected twice daily during the dosing period and animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in eggs, fat and muscle of poultry. Should the metabolism of asulam in ruminants or poultry be found to differ significantly from that in rats, studies on swine metabolism may be required.

3/ Residues of asulam in or on sugarcane samples must be subjected to analysis by multiresidue protocols. Protocols for methods I, II, III, and IV are available from the National Technical Information Service, 52285 Port Royal Road, Springfield, Virginia 22161. The Order No. is PB 203734/AS.

4/ All residue data requested in the registration standard must be accompanied by data regarding storage length and conditions of sample storage. The data must also be submitted depicting the stability of residues of asulam under the conditions and for the time intervals specified, if different than those discussed above. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field-weathered samples are used, the test substance must be a typical end-use product.

5/ Data must be submitting depicting asulam residues of concern in or on sugarcane harvested 90 days following the last of two postemergence broadcast applications (using ground and aerial equipment in separate tests) of the 3.34 lb/gal SC/L formulation at 3.34 lb ai/A. Tests must be conducted in Florida, Hawaii, and Louisiana, which collectively accounted for roughly 96% of total U. S. sugarcane production in 1985.

6/ Data must be submitting depicting concentration of asulam residues of concern in bagasse, molasses, and refined sugar processed from sugarcane bearing measurable, weathered residues. If residues concentrate in any processed product, an appropriate food/feed additive tolerance must be proposed.

7/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the requested animal metabolism studies the need for and nature of tolerances for residues in animal commodities will be determined and the need for additional feeding studies evaluated.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
Degradation Studies-Lab:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,D,G,H	No		Yes	9 Months
Photodegration:						
161-2 - In water	TGAI or PAIRA	A,B,D,G	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In air	TGAI or PAIRA	A	No		No1/	
Metabolism Studies- Lab:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G,H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D,G	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes	27 Months
Mobility Studies:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,D,G,H	Partially	00098525	Yes2/	12 Months
163-2 - Volatility (Lab)	TEP	A	No		No1/	
163-3 - Volatility (Field)	TEP	A	No		No1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.130 Environmental Fate (Continued)						
Dissipation Studies-Field:						
164-1 - Soil	TEP	A,B,H	No		Yes3/	-- Months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-4 - Combination and Tank Mixes	TEP				No1/	
164-5 - Soil, Long-term	TEP	A	No		Reserved 4/	
Accumulation Studies:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Yes5/	50 Months
165-3 - Irrigated Crops	TEP	D	No		Yes6/	39 Months
165-4 - In fish	TGAI or PAIRA	A,B,D,G	No		No7/	
165-5 - In Aquatic Nontarget Organisms	TEP	D,G	No		No8/	

1/ Data are not required to support current registered uses or are otherwise not applicable to this standard.

2/ Additional data are required on the soil degradation products of asulam (aged leaching), and batch equilibrium studies (adsorption/desorption) are needed on four soil types and a sediment.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

§158.130 Environmental Fate (Continued)

3/ Small scale prospective field leaching studies are required rather than new field dissipation studies. These will track the movement of asulam and its degradation products in soil, soil-pore water and shallow ground water in geographical areas of major usage. Protocols must be submitted within 90 days after receipt of this standard for approval before field work is begun. The Agency will provide the time frame for submission of the final report.

4/ Data may be required depending on the results of field dissipation studies and aerobic soil metabolism studies.

5/ Data are required since scientifically sound studies indicate that residues occur in rotated crops. If significant residues are found in rotated crops planted more than one year after application of assulam, tolerances for rotated crops will be needed.

6/ Data are required because asulam is used on ditchbanks which could serve as the source of irrigation water.

7/ No data are required because the octanol/water partition coefficient of asulam is significantly below 1000.

8/ No data are required because asulam does not accumulate significantly in fish tissue.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.135 Toxicology						
Acute Testing:						
81-1 - Acute Oral - Rat	TGAI		No		Yes	9 Months
81-2 - Acute Dermal	TGAI		No		Yes	9 Months
81-3 - Acute Inhalation - Rat	TGAI		No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI		Yes	00098534	No	
81-5 - Dermal Irritation - Rabbit	TGAI		Yes	00098535	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI		Yes	00098535	No	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI		No		No1/	
Subchronic Testing:						
82-1 - 90-day Feeding -						
Rodent	TGAI		No		No2/	
Non-Rodent	TGAI		No		Reserved 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.135 Toxicology (Continued):						
82-2 - 21-day Dermal - Rabbit	TGAI		No		Yes	12 Months
82-3 - 90-day Dermal	TGAI		No		No4/	
82-4 - 90-day Inhalation	TGAI		No		No4/	
82-5 - 90-day Neurotoxicity	TGAI		No		No1/	
Chronic Testing:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and			Yes	00098543	No	
- Non-rodent (Dog)			Partially	00098536	Yes3/	9 Months
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and			Yes	00098543	No	
- Mouse (preferred)			No		Yes	50 Months
83-3 - Teratogenicity - 2 Species:	TGAI					
- Rat			Yes	00098538	No	
- Rabbit			Yes	00098539	No	
83-4 - Reproduction	TGAI		Yes	00098540	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.135 Toxicology (Continued)						
Mutagenicity Testing:						
84-2 - Gene Mutation (Ames Test)	TGAI		No		Yes	9 Months
84-2 - Chromosomal Aberration	TGAI		Partially	00082250	Yes5/	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI		Yes	00098542	No	
Special Testing:						
85-1 - General Metabolism	PAI or PAIRA		No		Yes	24 Months

1/ There is no evidence of neurotoxic effects in mammaliam species from exposure to asulam. Therefore, this study is not required.

2/ The rat chronic toxicity study satisfies this requirement.

3/ EPA has a six-month dog study which was determined to be supplementary due to data reporting deficiencies. If the additional information the Agency requires can be provided, this study may be upgraded to satisfy both sub-chronic and chronic effects in the non-rodent. The following additional data must be submitted: (1) summary tables for urinalysis, plasma protein, coagulation studies, plasma and brain cholinesterase measurements (including a measure of variation such as standard error or standard deviation); (2) information on the sex of the animals in Tables 16 and 18 (mean absolute organ weights and mean organ/bodyweight ratio); and (3) actual number of tissues examined and individual pathology sheets.

4/ These data are not required because asulam's registered use patterns do not result in significant exposure.

5/ If individual animal data can be provided, this dominant lethal study may be upgraded to satisfy this requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP		N/A1/			
132-1 - Soil Dissipation	TEP		N/A1/			
133-3 - Dermal Exposure	TEP		N/A1/			
133-4 - Inhalation Exposure	TEP		N/A1/			
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP		N/A1/			
201-1 - Drift Field Evaluation	TEP		N/A1/			

1/ Data are not required since existing registered uses of asulam are such that significant exposure to workers or non-target organisms is not expected.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing:						
71-1 - Avian Oral LD_{50}	TGAI	A,B,D,G	Yes	00056417	No	
71-2 - Avian Dietary LC_{50}	TGAI	A,B,D,G	Yes	00056419 00056418	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,D,G	N/A1/			
71-4 - Avian Reproduction	TGAI	A,B,D,G	N/A1/			
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TGAI	A,B,D,G,	N/A1/			
Aquatic Organism Testing:						
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,D,G	Partially	00098505 00056421	Yes2/	9 Months
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,D,G	No		Yes	9 Months
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,D,G	Partially	00098508 00098509	Yes3/	12 Months
72-4 - Fish Early Like Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,D,G	N/A1/			

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms (Continued)						
Aquatic Organism Testing (Continued):						
72-5 - Fish - Life-Cycle	TGAI		N/A1/			
72-6 - Aquatic Organism Accumulation	TGAI		N/A1/			
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	N/A1/			

1/ Since there is no evidence that asulam poses a hazard to birds, fish, or mammalian species, these data requirements are not relevant.

2/ A study using a coldwater fish species is required.

3/ The requirement for a shrimp study is satisfied. An oyster study is required. If the freshwater fish LC_{50} (cold fish) study demonstrates a low toxicity then the marine fish study can be waived.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
Nontarget Insect Testing - Pollinators:						
141-1 - Honey Bee acute contact LD_{50}	TGAI	A,B,G,	Yes	00036935	No	
141-2 - Honey Bee - toxicity of residues on foliage	TEP	A,B,G	No		No1/	
141-4 - Honey bee subacute feeding study					Reserved2/	
141-5 - Field testing for pollinators	TEP	A,B,G	No		No1/	
Nontarget Insect Testing - Aquatic Organisms						
142-1 - Acute Toxicity to Aquatic Insects					Reserved3/	
142-2 - Aquatic Insect Life-Cycle Study					Reserved3/	
143-3 - Simulated or Actual Field Testing for Aquatic Insects					Reserved3/	
143-1 thru 143-3 - Nontarget Insect Testing - Predators and Parasites					Reserved3/	

1/ As data from the acute contact test indicate low toxicity, no further testing is required.

2/ Reserved pending development of test methodology.

Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
121-1 TARGET AREA PHYTOTOXICITY	TEP		No		No[1]	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Reserved[2]	
122-1 - Vegetative Vigor	TGAI	B,D,G	No		Reserved[2]	
122-1 - Aquatic Plant Growth	TGAI	B,D,G	No		Reserved[2]	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Reserved[3]	
123-1 - Vegetative Vigor	TGAI	B,D,G	No		Reserved[3]	
123-1 - Aquatic Plant Growth	TGAI	B,D,G	No		Reserved[3]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
TIER III						
124-1 - Terrestrial Field	TEP	B,D,G	No		Reserved[4/]	
124-2 - Aquatic Field	TEP	B,D,G	No		Reserved[4/]	

1/ Data are required only on a case-by-case basis.

2/ Growth and reproduction of aquatic plants seed germination/seedling emergence and vegetative vigor studies are reserved pending the results of asulam half-life in water and vapor pressure.

3/ Reserved pending results of Tier I.

4/ Reserved pending results of Tier II.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data Be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes3/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes4/	6 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis of Product Samples	MP	All	No	N/A	Yes5/	12 Months
62-2 - Certification of Ingredient Limits	MP	All	No	N/A	Yes6/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No	N/A	Yes7/	12 Months
Physical and Chemical Characteristics:						
63-2 - Color	MP	All	No	N/A	Yes8/	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes8/	6 Months
63-4 - Odor	MP	All	No	N/A	Yes8/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes8/	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
63-12 - pH	MP	All	No	N/A	Yes8/,9/	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes8/,10/	6 Months
63-15 - Flammability	MP	All	No	N/A	Yes8/,11/	6 Months
63-16 - Explodability	MP	All	No	N/A	Yes8/,12/	6 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes8/	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes8/,13/	6 Months
63-19 - Miscibility	MP	All	No	N/A	Yes8/,14/	6 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes8/	15 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	N/A	

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts Services (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ASULAM

§158.120 Product Chemistry (Continued)

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. Certifications should be submitted on EPA Form 8570, Rev. 2/85.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/ Upper and Lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA form 8570, Rev. 2-85.

7/ Anaytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explosivity, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

9/ Required if the test substance is dispersible with water.

10/ Required if the product contains an oxidizing or reducing agent.

11/ Required if the product contains combustible liquids.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ASULAM

§158.120 Product Chemistry (Continued)

12/ Required if the product is potentially explosive.

13/ Required if the product is a liquid.

14/ Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ASULAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	All	No		Yes	6 Months
81-2 - Acute Dermal	MP	All	No		Yes	6 Months
81-3 - Acute Inhalation - Rat	MP	All	No		Yes	6 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	No		Yes	6 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	No		Yes	6 Months
81-6 - Dermal Sensitization Guinea Pig	MP	All	No		Yes	6 Months

APPENDIX II

LABELING

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";
(B) "Among the least toxic chemicals known"
(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Au[illegible] 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR [illegible], Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products.

1. The labels of all products, except domestic use, must contain the statement:

   "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

   "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

   "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

APPENDIX III

USE INDEX

EPA Index to Pesticide Chemicals

ASULAM, SODIUM SALT

FINAL
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ASULAM, SODIUM SALT*

TYPE PESTICIDE: Herbicide

FORMULATIONS: SC/L (3.34 lb/gal or 36.2% a.i.)

GENERAL WARNINGS AND LIMITATIONS: A selective herbicide used in sugarcane, turf, ornamentals, noncrop areas, and reforestation areas. Do not apply directly to lakes, streams, or ponds, or contaminate water sources by cleaning of equipment or disposal of wastes. Apply when weeds are actively growing. An approved agricultural or non-ionic surfactant may be used in sugarcane and noncrop areas, respectively. The surfactant may be added to the finished spray solution at 0.25 percent by volume. Per acre dosages are for broadcast treatments, unless otherwise noted. For band or spot treatments, the dosages should be reduced proportionally. Dosages for this chemical were calculated using the asulam equivalent (a.e.).

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits meristematic cell division and expansion.

BROADLEAF WEEDS CONTROLLED:

BFAWBB	Canada thistle
BFAYBA	Horseweed
BFCXBC	Tansy ragwort

GRASSES AND OTHER MONOCOTS CONTROLLED:

CAARBC	Alexandergrass
CABHBB	Barnyardgrass
CAARBF	Broadleaf panicum
CACFBL	Bull paspalum
CABFAA	Crabgrass
CACEBD	Fall panicum
CACUAA	Foxtail
CABIBA	Goosegrass
CACOBA	Itchgrass
CACWBC	Johnsongrass
CABFBF	Large crabgrass
CAARBB	Paragrass
CAAWAA	Sandbur

*sodium salt of methyl sulfanilylcarbamate

ASULAM, SODIUM SALT

NONFLOWERING PLANTS CONTROLLED:

EBAHBC	Brackenfern
EBAHBB	Western brackenfern

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
25003AA	Sugarcane	0.1 (N) ppm 90 day preharvest interval. Do not graze or feed sugarcane fodder or forage to livestock.
	2.09-3.34 (3.34 lb/gal SC/L) 000359-00662	Postemergence. Broadcast or band. For control of alexandergrass, broadleaf panicum, crabgrass, foxtail, and goosegrass in plant cane or cane grown from stubble. Use the lower dosage when grass is less than 8 inches tall, or before seed head formation. Use the higher dosage when grass is taller than 8 inches or when grass is in early seed head formation. A second application may be made to crabgrass. Apply before seed head formation.
	2.51-3.34 (3.34 lb/gal SC/L)	Postemergence. Broadcast or band. For control of barnyardgrass in plant cane or cane grown from stubble. Use the lower dosage when grass is less than 8 inches tall, and the higher dosage when grass is taller than 8 inches. Do not make a second application during the growing season.
	3.34 (3.34 lb/gal SC/L)	Postemergence. Broadcast or band. For control of itchgrass, johnsongrass, and paragrass on plant cane or cane grown from stubble. Apply when grass is 6 to 24 inches tall. Apply in 15 to 100 gallons of water per acre by ground, or 3 to 5 gallons of water per acre by air (except in HI where 5 to 10 gallons of water per acre is recommended). A second application may be made to control itchgrass and johnsongrass. Make the second application at a rate of 1.67 to 3.34 pounds active ingredient per acre to johnsongrass between 18 and 24 inches tall, and at a rate of 3.34 pounds active ingredient per acre to itchgrass less than 12 inches tall.

ASULAM, SODIUM SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	Sugarcane (continued)	
	2.51-3.34 (3.34 lb/gal SC/L)	Postemergence. Spot treatment. Apply in 100 gallons of water. Do not exceed 50 gallons of finished spray per acre or 3.34 pounds active ingredient per acre per treatment.
	TERRESTRIAL NONFOOD CROP	
	(Ornamental Plants and Forest Trees)	
35315AA	Andorra Juniper	
35155AA	Chinese Juniper	
35160AA	Creeping Juniper	
35181AA	Intermediate Yew	
35072AA	Japanese Yew	
35073AA	Juniper	
35205AA	Savin Juniper	
35209AA	Shore Juniper	
35130AA	Yew	
35253AA	Yew Podocarpus	
	3.34 (3.34 lb/gal SC/L) 000359-00662	Postemergence. Broadcast. For control of barnyardgrass, crabgrass, fall panicum, foxtail, goosegrass, and horseweed. Make 1 application per year in a minimum of 20 gallons of water per acre when weeds are between early seedling and early seed head formation.
33017AA	Bermudagrass (Tifway 419)	General Information: Do not apply to freshly mowed turf or to turf under stress. Temporary turf discoloration may result.
33050AA	St. Augustinegrass	
	2.09 (3.34 lb/gal SC/L) 000359-00662	Broadcast. For control of bull paspalum, crabgrass, goosegrass, and sandbur. Make 1 application per growing season, when weeds are actively growing. Apply in 20 to 50 gallons of water per acre.
33017AA 33050AA	(Bermudagrass, St. Augustinegrass - golf course fairways and roughs)	
	[SLN] 1.67-2.09 (3.34 lb/gal SC/L)	SLN - Use limited to FL. Broadcast. For control of bull paspalum, crabgrass, goosegrass, and sandbur. Make 1 application per growing season. Apply in 30 to 50 gallons of water per acre. Use the higher dosage for control of goosegrass.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	Bermudagrass (Tifway 419) cluster (continued)	
3050AA	(St. Augustinegrass - for sod production)	
	[SLN] 2.09 (3.34 lb/gal SC/L)	SLN - Use limited to TX. Broadcast. For control of large crabgrass. Apply 20 gallons of finished spray per acre. Make 1 application per growing season.
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)	
70040A	Highway Rights-of-Way	
	2.92-3.34 (3.34 lb/gal SC/L) 000359-00662	Broadcast. For control of western brackenfern. Apply 20 to 100 gallons of finished spray per acre when the fern is in full frond.
	3.34-6.68 (3.34 lb/gal SC/L)	Broadcast or spot treatment. For control of crabgrass, johnsongrass, and paragrass. Apply 20 to 100 gallons of finished spray per acre before grasses reach seed head formation. For johnsongrass, apply when the grass is 18 inches or taller. Use the higher dosage in heavily infested areas. In HI, use the higher dosage and apply 100 gallons of finished spray as a spot treatment to control johnsongrass and paragrass. Do not exceed 50 gallons of total finished spray per acre.
	[SLN] 3.34 (3.34 lb/gal SC/L)	SLN - Use limited to CA (Del Norte County). Spot treatment. For control of tansy ragwort. Apply in 25 gallons of water. Make 2 applications per year. Do not exceed 3 pounds active ingredient per acre. Spray to wet foliage.
	[SLN] 1.67 (3.34 lb/gal SC/L)	SLN - Use limited to PA. Broadcast. For control of Canada thistle. Apply 25 gallons of finished spray per acre by ground or by air when thistle is between early and late bud stage. Make 1 application per growing season.
70000A 50130A	Noncrop Areas	General Information: Noncrop Areas include areas around boundary fences, fencerows, lumberyards, warehouse lots, utility yards, storage areas, industrial plant sites, utility, railroad, and pipeline rights-of-way.
	2.92-3.34 (3.34 lb/gal SC/L) 000359-00662	Broadcast. For control of western brackenfern. Apply 20 to 100 gallons of finished spray per acre when the fern is in full frond.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	Noncrop Areas (continued)	
	3.34-6.68 (3.34 lb/gal SC/L)	Broadcast or spot treatment. For control of crabgrass, johnsongrass, and paragrass. Apply 20 to 100 gallons of finished spray per acre before grasses reach seed head formation. For johnsongrass, apply when the grass is 18 inches or taller. Use the higher dosage in heavily infested areas. In HI, use the higher dosage and apply 100 gallons of finished spray as a spot treatment to control johnsongrass and paragrass. Do not exceed 50 gallons of finished spray per acre.
	[SLN] 3 (3.34 lb/gal SC/L)	SLN - Use limited to CA (Del Norte County). Spot treatment. For control of tansy ragwort. Apply in 25 gallons of water. Make 2 applications per year. Do not exceed 3 pounds active ingredient per acre. Spray to wet foliage.
	AQUATIC NONFOOD	
	(Aquatic Sites)	
650130A	Ditchbanks	
		Refer to TERRESTRIAL NONFOOD CROP, (Noncrop, Wide Area, and General Indoor/Outdoor Treatments), Noncrop Areas for pest and use information.
	FORESTRY	
30005AA	Christmas Tree Plantations	Do not graze or feed foliage from treated areas to livestock.
30004AA	Conifer Release	
30006AA	Forest Plantings (reforestation areas)	General Information: Apply in areas where Douglas-fir, grand fir, nobel fir, or scotch pine are grown.
	3.34 (3.34 lb/gal SC/L) 000359-00662	Postemergence. Broadcast. For control of western brackenfern. Apply 20 gallons of finished spray per acre by ground or 10 gallons of finished spray per acre by air after bud break and hardening, or firming of new tree growth. Apply when western brackenfern is in full frond.

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations

Christmas Tree Plantations cluster (continued)

[SLN] 1.67-3.34 (3.34 lb/gal SC/L)	SLN - Use limited to OR. Postemergence. Broadcast. For control of western brackenfern. Apply in 20 gallons of finished spray per acre by ground or 10 gallons of finished spray per acre by air after bud break and hardening, or firming of new tree growth. Apply when western brackenfern is in full frond.

35189AA (Jeffrey pine, ponderosa pine, red fir, sugar pine, white pine)
35100AA
35152AA
35228AA
35219AA

[SLN] 3.34 (3 lb/gal SC/L)	SLN - Use limited to CA. Postemergence. Broadcast. For control of western brackenfern. Apply in 20 gallons of finished spray per acre by ground or 10 gallons of finished spray per acre by air. Apply when western brackenfern is in full frond.

ASULAM, SODIUM SALT

Listing of Registered Pesticide Products by Formulation

36.2016 36.2% (3.34 lb a.e./gal) soluble concentrate/liquid

asulam, sodium salt (106902)

000359-00662

(000359-00662) CA810082 CA820028 CT800001 FL770005

FL780028 OR770033 PA810017 TX800005

ASULAM, SODIUM SALT

Auxiliary Documentation

Dennis Szuhay telecon (9-24-86) with Ms. McMullen - decided *Juniperus cuspidata* was a mistake and should have been a taxus. It will be removed in the next label revision.

use
130 Chem. Name: Asulam, Na salt

Date: 8/12/86

Chem No.: 106902

Product Total from Printout ________

Total Jackets Requested	Total Received	Number Used	Number Not Used

	Reg. #	PM	RB	Date Requested	Rec'd	N/A	Fiche Copy Date	Not Used	Comments
1	359-662	23			✓		3.34 lb/gal SC/L	(36.2%	[redacted]
2									
3	SLN								
4	CA 810082				✓				
5	CA 820028				✓				
6	CT 800001				✓				
7	FL 770005				✓				
8	FL 780028				✓				
9	OR 770033				✓				
10	PA 810017				✓				
11	TX 800005				✓				
12									
13									
14									
15									
16									
17									
18									
19									
20									

APPENDIX IV

BIBLIOGRAPHY

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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MRID	CITATION
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00004822	Guyton, C.L. (1977) Procedures for the Measurement of Asulam, MCPA, Sulfanilamide and Acetylasulam in/on Flax: Forages, Straw, Seed and Mill-Processed Flax Seed Fractions. Method no. 143 dated Jul 1977. (Unpublished study received Apr 13, 1979 under 359-662; prepared by Rhodia, Inc., submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:238025-B)
00004823	Carlyle, S. (1977) Sugarcane: Final Report No.: 330977-030. (Unpublished study including final report nos. 330977-031 and 330977-032, received Apr 13, 1979 under 359-662; prepared by Rhodia, Inc. in cooperation with United States Sugar Corp., submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL: 238025-C)
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000056417	Ingham, B. (1971) Herbicides: Asulox 40: Acute Oral Toxicity in Mallard, Partridges, Pheasants and Pigeons: Report No. RG/11 (Unpublished study received June 11, 1972 under 2G1200; prepared by May and Baker, Ltd., England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091017-T)
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00056421	Fraser, W.D.; Jenkins, G. (1970) The Acute Toxicity of Asulam to Rainbow Trout, Goldfish, Channel Catfish and Bluegill: Report No. 3639/70/451. (Unpublished study received Jun 11, 1972 under 2G1200; prepared by Huntingdon Research Centre, England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091017-X)
00056422	Lim, L. (1968) Herbicides: Studies with 35S-M&B 9057 (Asulam) in a Lactating Cow: PRG/73. (Unpublished study received Jun 11, 1972 under 2G1200; prepared by May & Baker, Ltd., England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091017-Y)

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00056435 Brockelsby, C.H. (1969) Asulam: Analytical Method for Residues in Plant Material: Report No. PRG.479. Method dated Jun 1969. (Unpublished study received Jun 14, 1972 under 2G1200; prepared by May & Baker, Ltd., England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091018-F)

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00056438 Brockelsby, C.H. (1971) Asulam: An Analytical Method for Residues in Sugar Cane: RG/1096. Method dated Jun 1971. (Unpublished study received Jun 14, 1972 under 2G1200; prepared by May & Baker, Ltd., England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091018-I)

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MRID	CITATION
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00056442	Brockelsby, C.H. (1971) Asulam (M&B 9057): Decline Studies on Sugar Cane: RG.975. Procedure dated Feb 1971. (Unpublished study received Jun 14, 1972 under 2G1200; prepared by May & Baker, Ltd., England, submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:091018-M)
00082250	Hastings, S.E.; Huffman, K.W. (1975) Dominant Lethal Study of Asulam in Mice: Report No. SEH 75:94. (Unpublished study received Dec 17, 1975 under 6F1717; submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:098085-E)
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00098505	Vilkas, A.G.; Kuc, W.J. (1979) The Acute Toxicity of Asulam Technical to the Bluegill Sunfish Lepomis macrochirus Rafinesque: UCES Project No. 11506-48-06. (Unpublished study received Apr 16, 1982 under 359-662; prepared by Union Carbide Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:070772-A)
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00113833	Stevens, K. (1971) Letter sent to C. Johnson dated Dec 27, 1971: Asulam--Working protocol. (Unpublished study received on unknown date under 2G1200; submitted by Rhodia, Inc., New Brunswick, NJ; CDL:097980-A)
00113836	Rhodia, Inc. (1972) Residues of Asulam in Sugarcane. (Compilation; unpublished study received on unknown date under 2G1200; CDL:097985-A)
00113837	Rhone-Poulenc, Inc. (1971) Study: Asulam Residue on Sugarcane. (Compilation; unpublished study received Jul 19, 1971 under unknown admin. no.; CDL:120793-A)
00136346	Brockelsby, C.; Crouch, R.; Marshall, R. (1971) Asulam: Residue Studies on Sugar Cane. (Unpublished study received 1971 under 2G1200; prepared by May & Baker Ltd., Eng., submitted by Florasynth, Inc., New York, NY; CDL:097986-A)

APPENDIX V

FORMS

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date _________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methos for enforce limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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Expiration Date 11/30/89

"GENERIC" DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________ and their registration number(s) is/are ____________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________
(Signature)

Dated: ______________ ______________________
(Typed)

EPA Form 8570-27